



STATE OF WASHINGTON
DEPARTMENT OF ECOLOGY

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August 6, 2014

Water Docket
Environmental Protection Agency
28221T
1200 Pennsylvania Ave. NW
Washington, DC 20460.

Attention: Docket ID No. EPA-HQ-OW-2014-0135.

Subject: Comments on “Updated National Recommended Water Quality Criteria for the Protection of Human Health.”(Federal Register /Vol. 79, No. 120 /Monday, June 23, 2014)

Dear Docket Manager:

Thank you for the opportunity to comment on EPA’s draft national recommended water quality criteria for human health, and for the 30-day extension granted on the original comment period. Ecology appreciates the significant effort EPA must have expended to develop the 94 draft criteria documents. Review of these new documents provides insight into how EPA sees the implementation of the EPA 2000 methodology for deriving human health criteria (USEPA, 2000) unfolding, which is very informative as Washington State develops its own human health criteria.

Attached are Ecology’s comments on the EPA draft national recommended water quality criteria for human health. If you have questions about the comments please contact Cheryl Niemi at cnie461@ecy.wa.gov or 360-407-6440. Thank you for taking these into consideration as you move forward in your process.

Sincerely,

A handwritten signature in black ink.

Melissa Gildersleeve, Manager
Watershed Management Section

Attachment A: Comments on the EPA draft national recommended water quality criteria for human health

Attachment B: Comments on EPA’s new FAQ: *Human Health Ambient Water Quality Criteria and Fish Consumption Rates, 4/17/2013 Frequently Asked Questions*

cc: Dan Opalski, EPA Region 10
Angela Chung, EPA Region 10
Matt Szelag, EPA Region 10



ATTACHMENT A: Comments on the EPA draft national recommended water quality criteria (NRWQC) for human health

Comment Category 1. The timing of the publication of the draft NRWQC and revision of the EPA 2000 *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*.

In a recent conference call with EPA headquarters staff and states on June 30, 2014, EPA staff stated that the agency plans to revise the 2000 EPA *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (USEPA, 2000; hereinafter called “EPA 2000 methodology”). When asked for specifics on timing of this revision effort, EPA stated that we might expect to see a notice of this effort as soon as 8 months from the time of the call, and that the process could potentially be concluded within 2 years. Given EPA’s stated intention to start revisions to the 2000 guidance within the next year, a partial revision of the recommended national criteria at this time does not make sense, since those same criteria would need to be recalculated using the updated methodology. From a resource standpoint for both EPA and the states, it makes more sense to conduct a major recommended criteria revision after revisions to the methodology are completed.

We suggest that EPA use the input it receives on these proposed draft recommended national criteria to inform the revision of the EPA 2000 guidance, rather than revising the recommended criteria at this time.

Comment Category 2: The Federal Register notice for the draft NRWQC, and intent statements for how recommended criteria are developed.

The federal register notice (Federal Register Volume 79, Number 92 (Tuesday, May 13, 2014) says: “*Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects*” and “*... States and authorized Tribes have the discretion to adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.*”

Comment 2a. Contrary to the statement in the federal register notice, we note that EPA human health criteria guidance values are based on more than data and scientific judgments. The guidance values are based on science, science policy, and risk management. This is explained in the EPA 2000 methodology at Sec. 2.2 Science, Science Policy, and Risk Management. EPA should be clear in Federal Register information and other communications around the draft NRWQC notices that significant risk management decisions as well as science and science policy are included in its development of 304(a) human health criteria. We recommend that the specific language describing science, science policy, and risk management be taken from the 2000 guidance and used to clarify future Federal Register notices and other communications so that it is not misinterpreted that values are based solely on data and scientific judgment.

Comment 2b. States’ policy discretion needs acknowledgement: States have discretion to develop and adopt WQC that differ from national recommended criteria based not just on science, but also on state-specific science policy and risk management choices and decisions. This is consistent with 40CFR131.11(b). We recommend that this be clarified in future Federal Register notices.

Although the Federal Register notice only invites comments based on science, we want to reiterate comments we have made to EPA on previous occasions regarding specific risk management decisions that are most appropriately made by states and not by EPA:

- i. **Relative Source Contribution (RSC).** As discussed with EPA on previous occasions, using a RSC to calculate human health criteria in order to account for exposures to pollutants that are not related to Clean Water Act (CWA) geographic jurisdiction or to CWA regulatory tools is clearly

a state-specific risk management decision, and should be acknowledged as such by EPA in both guidance and in Federal Register notices. Attachment B provides more detail on why Washington has serious reservations about using a RSC as described in the 2000 methodology, the 2013 Frequently Asked Questions document produced by EPA, and as incorporated into the draft NRWQC. Comment 4c(iv) below also has related information regarding use of BAFs.

- ii. **CWA criteria and tools.** We suggest that the CWA criteria should fit the CWA tools, otherwise, unrealistic expectations will be raised about the ability of NPDES dischargers to effect clean-up when they are not responsible for, nor have control of, the sources of pollutants. We suggest that discussion around this concept, which is complex, would be appropriate to have when EPA revises their EPA 2000 methodology for human health criteria development. The goal of the criteria is to protect the designated uses. How to effect pollution prevention at the point where pollutant reductions can be made, without placing responsibility on parties that are not the ones producing or discharging the pollution entering the fish, shellfish, and drinking water, is a topic that would be ripe for national discussion. This discussion would of necessity be broad, and should include other regulatory programs (i.e. Air, Superfund) that address sources of pollutants that are outside the CWA and that affect surface waters.

Comment Category 3: Supporting information for the draft NRWQC. Several changes to the draft NRWQC are not explained adequately in the draft criteria documents, the Federal Register notice, or accompanying material, thus making adequate review by states and others unworkable.

The Federal Register notice says: “*EPA has updated the draft human health criteria using information sources and models that have previously undergone external peer review*” and “*The support documents detail the latest scientific information supporting the updated draft human health criteria, particularly the updated toxicity and exposure input values.*”

EPA used a substantial amount of new science and science policy in these drafts. This includes newly calculated BAFs, a new fish consumption rate (FCR), and other factors. The Federal Register notice indicates that this new information was subject to external peer review. That is good to know, but uninformative as far as supporting a state’s decision to use the information. Peer review comments can be used or rejected by authors, and the acceptance or rejection process can dictate in large part the type of product that emerges.

- An example of this is the new drinking water intake rate of 3 L/day used in the draft guidance calculations. The 3 L/day was developed from the *2011 Exposure Factor’s Handbook* (USEPA, 2011), which provides a range of values reflecting adult, direct and indirect (water added in the preparation of a food or beverage) consumption of water, 90th percentile values. The values range from 2.1 to 3.1 liters per day. There is no explanation of how and why EPA settled on the value of 3 L/day, therefore we are not able to determine if the new value is meaningful to our state or not, or why another value was not used. See additional comments below on 4a, drinking water intake.

Comment 3a. Overall, this public notice and the draft documents did not provide adequate supporting information for Ecology to review and provide meaningful comments on the newly proposed 94 chemical criteria recommendations. EPA needs to carefully explain the processes used to develop the new values derived in the draft criteria documents. In order to allow adequate review of the recommended criteria, we request that EPA prepare one document that comprehensively explains the development of the new information, including information about the external peer reviews and a discussion of why the new information and tools are best/good enough/appropriate for use in calculating guidance values. The text from a summary document that addresses overall new science, science policy, and EPA risk management

approaches could be included in the draft criteria documents, or could be cited within the draft criteria documents. The document should include:

- i. Identification of the science/science policy/ and risk management calls (and rationale) that EPA used to apply this newer information in the context of its EPA 2000 guidance.
- ii. An explanation of how the newer information differs from the information used to calculate the current recommended criteria. For instance – the EPA IRIS process is documented, transparent, and most states are familiar with it. In order for states and others to compare the current numbers with the newly proposed numbers, EPA needs to explain how the non-IRIS processes used to develop many of the new toxicity factors differ from IRIS and how they are the same. It is also important to include an explanation of the peer review process for the non-IRIS processes.
- iii. An explanation of the pros and cons of choosing from an array of different sources of CSFs and RfDs, and model derived BAFs vs. lab derived BCFs.

Comment 3b. Ecology recommends that EPA provide updated versions of the 2002 Calculation Matrix (USEPA, 2002) to accompany all major updates to the national recommended human health criteria. The 2002 Matrix is a valuable resource for states, and its development after the last major revision (2002 recalculation) of the national recommended criteria (using the 2000 guidance, with new toxicity factors and a new 17.5 g/day FCR) was welcome additional information on criteria calculation. We recommend that these revisions of the Matrix live as stand-alone documents – similar to the Red Book and Gold book. This type of information compilation is invaluable when the histories of individual chemical criteria are being followed.

Comment Category 4. Comments on specific variables in the equations:

Comment 4a. Drinking Water Intake (DI). EPA's most recent *2011 Exposure Factors Handbook* (USEPA, 2011; Tables 3-10, 3-26, and 3-27) provides examples of updated 90th percentile adult (ages 18-65) DI values between 2.1 and 3.1 liters/day, based on national data. These values are for direct and indirect (water added in the preparation of a food or beverage) consumption of water, and are further explained in the tables specified above from the *2011 Handbook*.

EPA released new *Supplemental Guidance for Superfund* on February 6, 2014 (memo from Dana Stalcup, USEPA to Superfund National Policy Managers, Regions 1-10; OSWER Directive 9200.1-120) that incorporates and adopts updates to *Risk Assessment Guidance for Superfund: Human Health Evaluation Manual, Part A through E*, based on data in the *2011 Exposure Factors Handbook*. This includes a recommended 90th percentile adult drinking water intake value of 2.5 L/day. The new draft national recommended human health surface water criteria, published in May 2014, include use of a 90th percentile adult drinking water intake value of 3.0 L/day, based on data in the *2011 Exposure Factors Handbook*. Both of these values are derived from the *2011 Exposure Factors Handbook*, but the Handbook itself does not provide a single recommended value for this variable (as it does for body weight). For decades the recommended DI values used for CWA criteria development and Superfund risk assessment have been the same value (2 L/day).

Before we can adequately review the new DI used in the calculation of the 94 chemicals, we need an explanation from EPA on why these two new values differ from each other, and the science, science policy, and risk management considerations included in determining why, or why not, one might be more appropriate for CWA criteria development than the other.

Comment 4b. Toxicity factors

The CSFs and RfDs used in the criteria are taken from what appears to be a broad array of sources (for example, see the gamma-BHC (Lindane), dichlorobromomethane, and chrysene draft criteria documents). Except for IRIS, we do not know the development process or type of scientific/peer review associated

with these different sources (see also: Comment Category 3 above). We request that EPA address the following when explaining how the draft criteria were developed, so that adequate review can occur:

- i. EPA has a hierarchy for CSF/RfD values that it uses for Superfund. An explanation needs to be provided of whether EPA also depended on a hierarchy for choosing toxicity values for these draft CWA criteria, and if so, what the hierarchy is and the rationale behind it. In past iterations of NRWQC development, EPA has used some non-IRIS values. States and others need some explanation of the rationale for this so that we can understand and adequately review and comment on the resulting decisions.
- ii. An explanation of the public and scientific process that was used to develop the non-IRIS values, and what level of review was included. It is also important to understand where these other sources would sit in a hierarchy. Factors of importance would include: more or less public review, Science Advisory Board participation, uncertainty factors (representing the types of uncertainty and what magnitude of change results from uncertainty factor use), overall confidence in the resultant toxicity factor, transparency of process, data quality, etc.).
- iii. EPA used a new approach for criteria development for the PAHs (e.g., chrysene, as copied below; USEPA, 2014). The use of Potency Equivalency Factors (PEFs) based on benzo(a)pyrene is not an approach used before for criteria development. Before we can adequately review, we need more information on whether IRIS is reviewing this approach or the toxicity factors for the PAHs. This approach seems similar to the TEQ and TEF approach sometimes used for dioxin, but EPA has not moved forward with use of that approach for dioxin criteria development. It seems inconsistent that EPA is now proposing the PEF approach for PAHs and not for dioxin, so an explanation of this discrepancy is needed before we can fully review the new approach.

Excerpt from draft chrysene NRWQC document (USEPA, 2014):

"The cancer slope factor (CSF) is an upper bound, approximating a 95% confidence limit, on the increased cancer risk from a lifetime oral exposure to an agent. The previously used CSF for chrysene was the CSF for benzo(a)pyrene of 7.3 per mg/kg·day (USEPA, 1994a; USEPA, 2002b). In 2010, the California Environmental Protection Agency Office of Environmental Health Hazard Assessment updated the toxicology assessment for benzo(a)pyrene. That assessment (OEHHA, 2010), which has been subject to internal and external peer review, provides the basis for the updated CSF of 2.9 per mg/kg·day. The California Environmental Protection Agency Office of Environmental Health Hazard Assessment also published a potency equivalency factor (PEF) for chrysene in relation to benzo(a)pyrene of 0.01 (California Air Resources Board and OEHHA, 1994; OEHHA 2005). This results in a CSF of 0.029 per mg/kg·day for chrysene.

The principle study by Culp et al. (1998) chosen to calculate the cancer slope factor for benzo(a)pyrene was based on development of tumors of the forestomach, tongue and esophagus in female mice orally exposed to benzo(a)pyrene (OEHHA, 2010). The study by Culp et al. resulted in an unadjusted CSF of 1.7 per mg/kg·day, but an age sensitivity factor (ASF) was applied due to benzo(a)pyrene's mutagenic mode of action, resulting in the adjusted CSF of 2.9 per mg/kg·day for benzo(a)pyrene. Multiplication of the PED for chrysene of 0.01 by the CSF of 2.9 per mg/kg·day results in the CSF of 0.029 per mg/kg·day for chrysene used in the criteria calculations."

Comment 4c. Bioaccumulation Factors

EPISuite is a new tool for states and others to assess and review. We have not had time to review this in any detail and have only very general questions based on a rapid perusal of EPA's EPISuite web page. Use of this model for criteria development prompts a number of questions regarding both the current and proposed criteria that need further explanation by EPA before a more detailed review of this new tool can occur:

- i. Explain how this tool was developed. Include explanation of public and scientific review that were associated with it, and a general discussion of its basis.
- ii. Identify the limitations of this tool. The EPA website indicates it should be used for "screening", but it is being proposed for use here for criteria development, which if used for state-adopted criteria could result in direct regulatory levels in the water column, with possible significant costs to states and dischargers resulting from 303(d) listings, TMDLs, and subsequent effluent limits. States and others need to know if this "screening tool" is dependable/certain enough to base these types of requirements on.
- iii. Please describe how this model was calibrated, and an explanation of its applicability for nationwide use. It is also important to understand what types and levels of uncertainty are associated with use of this model.
- iv. We need to understand why EPA chose to go with a BAF model instead of using lab-derived BCFs, which we believe more closely reflect the exposure of the fish to the water itself (not full environmental exposure which includes atmospheric deposition that enters waterbodies, food web transport that could originate from sediments, oceans, or other sources, etc.). We assert that BCFs could, for many chemicals, be a closer match to the regulatory and implementation tools that the CWA provides for states. Using a BAF for criteria purposes could be interpreted as assuming that CWA pollution prevention tools (e.g., NPDES permits) can actually regulate these other sources. Please explain the rationale behind the proposed criteria and how they can be attained using CWA tools. In particular, legacy pesticides are of interest. (This is an area that will be ripe for discussion when EPA revises its EPA 2000 guidance).

We believe there could be useful national discussion of this concept on a chemical specific basis (see comment 4c.vii below). Pollutants take different paths to tissue based on their chemical characteristics. If a pollutant is largely from direct CWA-regulated discharges to waters, and the food web path goes from that water concentration to the organism, without large input from other non-CWA sources that are either actively entering the water column or from other sources already sequestered in the environment from past activities, a BAF might be most reflective of the sources regulated under the CWA. In other cases a BCF might be most representative of CWA-regulated discharge sources when other greater pathways to fish lead from non-CWA sources or legacy sources already sequestered into, and then re-sourcing to organisms, from different environmental media.

- v. An explanation of whether this new tool has been used by other states in developing criteria for their state.
- vi. We know that BAFs vary from waterbody to waterbody, and even within waterbodies. If states choose to use BAF values from the EPISuite tool, we are interested in knowing whether the tool can be used to develop tailored BAFs for a state, and whether EPA would recommend that states do this.
- vii. The BCF values in the current criteria are quite old, and sometimes based on just one species (e.g. the acrolein BCF of 215). However, they have been used for years and have been part of CWA-approved criteria. Both the older BCFs and the proposed BAFs have uncertainties associated

with them. In order to compare the two, we need to understand what science, science policy, and risk management choices and decisions were made by EPA as the BCF/BAF variable was considered. We would like EPA to consider whether it is possible that for some pollutants an older BCF would be more appropriate and for others a newer model-derived BAF would be better (please see comment 4c.iv above). Perhaps, as discussed above, the use of BAF or BCF, on a chemical specific basis, should be associated with the sources and pathways of the pollutant to the water column and organisms, and the ability of CWA and different regulatory programs to address the sources.

- viii. Application of trophic level BAFs to FCRs: state-specific FCR data will often not support this detailed type of "allocation." If states want to use state-specific FCR data and choose to use EPISuite BAFs, but do not have the resolution on ingested species and trophic levels that would make application of the three trophic level BAFs possible, EPA needs to advise states on how they expect that EPISuite BAFs would be applied.

Comment 4d. Fish Consumption Rate

The new proposed fish consumption rate of 22 g/day is based on a modified and shortened version of the NCI method. Reviewers (for example, Janet A. Tooze, Ph.D., M.P.H., one of the primary authors of the NCI Method) expressed some degree of uncertainty around use of this newer EPA approach. According to the response to comments, EPA made the choice to use the shortened method because of time constraints and computing power, the resulting values seemed to correspond well with NCI results, and because the information that they used was only available at a specific location, and not publically available. This newer approach and the new proposed rate, as well as the draft criteria, would benefit by more explanation that addresses the following:

- i. If the data are not publically available, explain how the work can be replicated by other parties.
- ii. More description on whether assuming a probability of consuming fish = 1 results in an overestimation and/or underestimation of the rate, and if so, at what parts of the distribution do the over or under estimations occur (lower, mid, or upper percentiles).
- iii. The geographic and demographic breakdown categories addressed in the report are very useful information. Please provide the FCR data, by percentiles, for the entire FCR distribution, and for the geographic/demographic breakdowns provided in the report. The report does not provide FCRs at lower percentiles (e.g., 0, 1st, 3rd, 5th, 10th, etc...). As required by Washington State's Administrative Procedures Act, agencies in Washington must conduct a Cost Benefit Analyses for any significant rule revision. We do not know if many other states have this requirement; however, Washington needs a complete distribution of fish consumption rates in order to estimate costs and benefits for the state's population when adopting new human health criteria. Having this information, as well as the information currently contained in the report, would help facilitate rule adoption.
- iv. An explanation of how the distribution from this new approach compares to the distribution that would result from the old approach. This information would be very valuable because it would give states some sense of how different the new approach is from that used previously.
- v. Given a new set of data and analysis, EPA needs to explain why this is not also resulting in new recommendations for recreational and subsistence fishers.

References

- USEPA, 2000. U.S. Environmental Protection Agency. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, (EPA-822-R-00-004).
- USEPA, 2002. U.S. Environmental Protection Agency. *National Recommended Water Quality Criteria: 2002 Human Health Criteria Calculation Matrix*. EPA-822-R-02-012 . November 2002
- USEPA, 2011. U.S. Environmental Protection Agency. *EPA Exposure Factors Handbook - 2011 edition* (EPA 600/R-090/052F).
- USEPA, 2014. U.S. Environmental Protection Agency. *Draft Update of Human Health Ambient Water Quality Criteria: Chrysene 218-01-9*. EPA 820-D-14-029. May 2014

ACWA Monitoring, Standards & Assessment Committee Call
Wednesday, April 17, 2013

Subject: Discussion on EPA's new FAQ: *Human Health Ambient water Quality Criteria and Fish Consumption Rates Frequently Asked Questions*: <http://water.epa.gov/scitech/swguidance/standards/criteria/health/methodology/upload/hhfaqs.pdf>

Comments from Washington & Idaho:

Cheryl Niemi, Washington Department of Ecology, cnie461@ecy.wa.gov

Don Essig, Idaho Department of Environmental Quality, don.essig@deq.idaho.gov

Overall comment:

Several states are dealing with development of human health criteria as they revise standards. Washington and Idaho are both starting the process and are dealing with particularly complex issues because of abundance of fisheries for anadromous fish, subpopulations that consume large amounts of anadromous and local fish and shellfish, a lack of state-specific data on the fish and shellfish consumption patterns of the general population, and a very motivated and concerned set of stakeholders who all have important interests to address. In addition, in Idaho and Washington there have been recent communications with EPA Region 10 that indicate that EPA is considering development of regional guidance or other decision-making processes on human health criteria development that could seriously affect the ability of the states to make the risk management decisions that have historically and appropriately been made by states – decisions on such issues as risk levels and fish consumption rates. This had led to an uncertain rule-making environment, and a real concern that EPA might develop guidance that could act as rule. Launching this FAQ into such a highly charged environment, without the benefit of state review and consideration of the issues being addressed in state rule-makings, is of significant concern.

Specific comments:

In the left column below is a copy of the EPA FAQ. The FAQ is divided below into a table format to facilitate discussion of individual Question/Response topics. State comments/concerns with the information in the FAQ are in the right column. Specific comments in each section are numbered across the columns to clarify the linkage between highlighted FAQ language and state comments/concerns.

<p>Document Title:</p> <p><i>Human Health Ambient water Quality Criteria and Fish Consumption Rates Frequently Asked Questions</i></p> <p><i>[Note: the answers below reflect existing EPA policy and guidance, as articulated in the 2000 Human Health Methodology]</i></p>	<p>Abbreviations:</p> <p>HHC – Human health criteria, WQS = water quality standards, SDWA = Safe Drinking Water Act, CWA = Clean Water Act, RSC = Relative Source Contribution, MCLG = Maximum Contaminant level Goal, MCL = Maximum Contaminant Level</p>	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center; width: 30%;">EPA FAQ Language</th><th style="text-align: center; width: 30%;">State Comment/concern</th></tr> </thead> <tbody> <tr> <td style="padding: 5px;"><i>This guidance does not have a disclaimer.</i></td><td style="padding: 5px;"> <p>EPA's new FAQ on multiple discharger variances (EPA-820-F-13-012, March 2013) contains some introductory language that clarifies the role of that FAQ – explaining that it is guidance and not rule. A similar disclaimer is desirable for this Fish Consumption Rate FAQ (EPA variance FAQ language below):</p> </td></tr> </tbody> </table>	EPA FAQ Language	State Comment/concern	<i>This guidance does not have a disclaimer.</i>	<p>EPA's new FAQ on multiple discharger variances (EPA-820-F-13-012, March 2013) contains some introductory language that clarifies the role of that FAQ – explaining that it is guidance and not rule. A similar disclaimer is desirable for this Fish Consumption Rate FAQ (EPA variance FAQ language below):</p>	<p>DISCLAIMER <i>These Frequently Asked Questions (FAQs) do not impose legally binding requirements on the EPA, states, tribes or the regulated community, nor do they confer legal rights or impose legal obligations upon any member of the public. The Clean Water Act (CWA) provisions and the EPA regulations described in this document contain legally binding requirements. These FAQs do not constitute a regulation, nor do they change or substitute for any CWA provision or the EPA regulations. The general description provided here may not apply to a particular situation based upon the circumstances. Interested parties are free to raise questions and objections about the substance of these FAQs and the appropriateness of their application to a particular situation. The EPA retains the discretion to adopt approaches on a case-by-case basis that differ from those described in these FAQs where appropriate. These FAQs are a</i></p>
EPA FAQ Language	State Comment/concern						
<i>This guidance does not have a disclaimer.</i>	<p>EPA's new FAQ on multiple discharger variances (EPA-820-F-13-012, March 2013) contains some introductory language that clarifies the role of that FAQ – explaining that it is guidance and not rule. A similar disclaimer is desirable for this Fish Consumption Rate FAQ (EPA variance FAQ language below):</p>						

	<p><i>Living document and may be revised periodically without public notice. The EPA welcomes public input on these FAQs at any time.</i></p>
Q1. What is the goal of the human health ambient water quality criteria?	<p>Clean Water Act (CWA) section 303(c)(2)(A) requires that water quality standards (WQS) protect “public health or welfare, enhance the quality of the water and serve the purposes of [the Act].” CWA section 101(a)(2) establishes as a national goal “water quality which provides for protection and propagation of fish, shellfish, and wildlife, and recreation in and on the water, wherever attainable.” EPA has interpreted the “fishable” language in section 101(a)(2) to refer not only to protecting water quality so the fish and shellfish thrive, but when caught they can also be safely eaten by humans. Thus, to be consistent with section 101(a)(2), the applicable criteria for such “fishable” designated uses must not only protect the aquatic organisms themselves, but also protect human health through consumption of fish and shellfish.¹</p> <p>Comment 1.</p> <p>Suppression effects are a very sensitive topic for many groups in the Pacific Northwest, and it is difficult to apportion the amount of suppression caused by different factors. Unfortunately the concepts of <i>availability</i> of fish and <i>contamination</i> of fish get mixed up. Some specific language here that speaks directly to the possible causes of suppression, and then directly pinpoints the suppression linked to contamination, would be useful for readers.</p> <p>It would also be helpful to acknowledge the difficulty in accurately quantifying suppression.</p>

expects that the standards will be set to enable residents to safely consume from local waters the amount of fish they would normally consume from all fresh and estuarine waters (including estuarine species harvested in near coastal waters). EPA does not necessarily expect all consumers to eat only fish from a single State, but individuals or groups should be able to do so without concern for their health. (see comment 1 at right) It is also important to avoid any suppression effect that may occur when a fish consumption rate for a given subpopulation reflects an artificially diminished level of consumption from an appropriate baseline level of consumption for that subpopulation because of a perception that fish are contaminated with pollutants.

This approach is consistent with a principle that every State does its share to protect people who consume fish and shellfish that originate from multiple jurisdictions. In addition, the goal of water quality criteria for human health is to protect people from exposure to pollutants through fish and water over a lifetime, and the goal of a State's designated use should be that the waters are safe to fish in the context of the total consumption pattern of its residents. Likewise, because people are expected to continue consuming fish and shellfish throughout their lifetime regardless of where they live, and this consumption leads to similar exposure to pollutants, it is appropriate to derive protective human health criteria in State and Tribal water quality standards assuming a lifetime of exposure.

Although the human health ambient water quality criteria (AWQC) are based on chronic health effects data (both cancer and noncancer effects), the criteria are intended to also be protective against adverse effects that may reasonably be expected to occur as a result of elevated acute or short-term exposures.

	<p>Q2. What does the fish consumption rate (FCR) indicate in the calculation for human health ambient water quality criteria?</p> <p>The FCR indicates the amount of fish and shellfish in kilograms consumed by a person each day. For the purposes of human health ambient water quality criteria, the fish and shellfish to be reflected in the FCR include all of the fish and shellfish consumed that are species found in fresh and estuarine waters (including estuarine species harvested in near coastal waters). (see comment 1 at right) Because the overall goal of the criteria is to allow for a consumer to safely consume from local waters the amount of fish they would normally consume from all fresh and estuarine waters, the FCR does include fish and shellfish from local, commercial, aquaculture, interstate, and international sources. It is not necessary for the FCR to include fish and shellfish species designated as marine species, as that exposure is addressed by relative source contribution (see question 4 for more detail). However, partitioning of fish and shellfish into the different habitats in order to develop a FCR can only be done where sufficient data are available for this to be done in a scientifically defensible manner.</p> <p>For example, if a State were to determine through scientifically collected data that its citizens consumed 25 grams of fish and shellfish per day where 5 grams came from marine fish, 5 grams came from a local fresh water stream (see comment 1 at right) 5 grams came from a neighboring state's fresh waters, 5 grams came from international imports of estuarine shellfish, and 5 grams came from aquaculture of a freshwater species, then the FCR would be 20 grams per day. Only the marine fish component would be excluded from the FCR (see discussion below on relative source contribution). (see comment 2 at right) All of the other</p> <p>Comment 1. If the overall goal is to allow consumers to safely consume freshwater and estuarine fish resources from local waters, then including all the fish and shellfish consumed from interstate and international sources does not make sense. The amount of consumption associated with the commercial availability of these sources does not necessarily reflect the amount of fish or shellfish that are, were, or might be attainable in local waters. For instance, a person from a state with no marine coastline might eat large amounts of prawns and bivalves harvested in a foreign country and purchased at the supermarket. This consumption does not reflect exposures from local waters or the fishery resources that would naturally be there. This consumption should be considered during the development of the RSC (if data are available to document contaminants in these new fishery sources (such as mercury in tuna)), but not in the overall FCR.</p> <p>Aquaculture resources are complex. Many types of aquaculture are practiced. Some types are almost completely dependent on the local waters for support (e.g. oyster industry), others use a mixture of in-situ exposure of local water and commercial or proprietary feed stock (e.g. net pens), and still others use upland facilities with waters piped to the facility in a manner analogous to industrial water use and combined with commercial or proprietary feed stock (upland facilities raising tilapia). The first type of aquaculture venture could closely fit the definition of locally harvested resources, the second is more ambiguous, and the third is more similar to an industrial operation and not a local waterbody harvest issue. Including all resources from aquaculture in the FCR does not take the complexity of these different types of exposure sources into</p>
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<p>components represent the amount of fish and shellfish that could be taken and consumed from local waters if the consumer chose to do so.</p> <p>Comment 2. The last sentence states that all of the “components represent the <u>amount of fish and shellfish that could be taken and consumed from local waters if the consumer chose to do so.</u>” This does not make sense. The international and national market for fisheries has created a market situation where people who previously would have little harvest available locally could (by eating commercially available non-local fish or shellfish) enhance their consumption to levels that would more closely mirror locally supported consumption patterns in areas with locally abundant fishery resources – but do not mirror the “amount of fish and shellfish that could be <u>taken and consumed from local waters if the consumer chose to do so.</u>”</p>	<p>No comment.</p>
<p>Q3. How is the exposure to a pollutant due to marine fish consumption accounted for in the human health ambient water quality criteria?</p> <p>Human health ambient water quality criteria are to account for all sources of exposure to the pollutants for which they are developed. The exposure to pollutants from marine fish and shellfish species that are not included in the fish consumption rate should be accounted for in the relative source contribution (RSC) when setting criteria for threshold non-carcinogens and non-linear carcinogens.</p>	

<p>Q4. What does the relative source contribution (RSC) indicate in the calculation for the human health ambient water quality criteria?</p>	<p>The relative source contribution component of the human health ambient water quality criteria (AWQC) calculation for threshold non-carcinogens and non-linear carcinogens allows a percentage of the reference dose's exposure to be attributed to ambient water and freshwater and estuarine fish consumption (including estuarine species harvested in near coastal waters) when there are other potential exposure sources. (see comment 1 at right) The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. The RSC includes, but is not limited to, exposure to a particular pollutant from marine fish consumption (not included in the fish consumption rate), non-fish food consumption (fruits, vegetables, and grains), dermal exposure, and respiratory exposure.</p> <p>In the absence of scientific data, the application of the EPA's default value of 20 percent RSC in calculating 304(a) criteria or establishing State or Tribal water quality standards under Section 303(c) will ensure that the designated use for a water body is protected. (see comment 2 at right – boldface added) This 20 percent default for RSC can only be replaced where sufficient data are available to develop a scientifically defensible alternative value. If appropriate scientific data demonstrating that other sources and routes of exposure besides water and freshwater/estuarine fish are not anticipated for the pollutant in question, then (see comment 3 at right – boldface added) the RSC may be raised to the appropriate level, based on the data, but</p> <p>Comment 1. The 20%/80% RSC approach in the EPA 2000 guidance was developed as part of a process to "harmonize" the SDWA and the CWA. See EPA 2000 (bottom of page 1-5):</p> <p><i>"Another reason for the 2000 Human Health Methodology is the need to bridge the gap between the differences in the risk assessment and risk management approaches used by EPA's Office of Water for the derivation of AWQC under the authority of the CWA and Maximum Contaminant Level Goals (MCLGs) under the Safe Drinking Water Act (SDWA). Three notable differences are the treatment of chemicals designated as Group C, possible human carcinogens under the 1996 proposed cancer guidelines, the consideration of non-water sources of exposure when setting an AWQC or MCLG for a noncarcinogen, and cancer risk ranges."</i></p> <p>The SDWA MCLG derivation procedures use a 20%-80% approach. Applying this RSC range to CWA HHC provides some harmonization between the two Acts, but does not take into account that the MCLG is not a regulatory level (it is a goal), and that the CWA human health criteria (HHC) are regulatory levels enforced both as ambient concentrations in the water body (303(d) listing process and through NPDES permit limits.) Under the SDWA the MCLG is modified to create an at-tap regulatory level (the maximum contaminant level - MCL) by taking into account factors such as available treatment and available analytical methods. Here is an example for nitrate taken from EPA's website (boldface added) at http://water.epa.gov/drink/contaminants/basicinformation/nitrater.cfm that gives some explanation of how MCLs are</p>
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<p>not to exceed 80 percent. The 80 percent ceiling accounts for the fact that some sources of exposure may be unknown. In cases where an 80 percent RSC is used, 20 percent of the exposure is reserved for unknown sources. Although the 20 percent RSC has not been consistently applied to national 304(a) criteria recommendations for non-carcinogenic pollutants, where there are inconsistencies between the 2000 Human Health Methodology recommendation and implementation in criteria, the Human health Methodology should prevail and the 20 percent RSC applied. EPA is moving to complete implementation of this guidance in existing 304(a) criteria.</p>	<p>developed from MCLGs:</p> <p><i>"The MCLG for nitrate is 10 mg/l or 10 ppm. EPA has set this level of protection based on the best available science to prevent potential health problems. EPA has set an enforceable regulation for nitrate, called a maximum contaminant level (MCL), at 10 mg/l or 10 ppm. MCLs are set as close to the health goals as possible, considering cost, benefits and the ability of public water systems to detect and remove contaminants using suitable treatment technologies. In this case, the MCL equals the MCLG, because analytical methods or treatment technology do not pose any limitation."</i></p>	<p>NPDES permitting tools can sometimes accommodate some of these considerations during implementation, but final limits must always be based on the HHC. The larger reason why the MCLG does not mirror the HHC is that the MCLG is not in itself a level that must be attained, while the HHC is always a level that must be attained in ambient waters. The roll-out of this difference is apparent with the application of the 303(d) program, the requirement for allocation of loads, and subsequent permitting requirements found at 40 CFR 122.4(i) and the Pinto Creek decision (http://cdn.ca9.uscourts.gov/datasstore/opinions/2007/10/03/0570785.pdf). In this context, the HHC themselves are strong regulatory numbers that drive resource intensive programs.</p>	<p>This is important because the risk management/policy decision to use a RCS of 20% to 80% in the MCLG itself has no regulatory outcome – it simply provides a backdrop</p>
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for development of the MCL. The risk management/policy decision to use a 20% to 80% RSC in HHC development directly affects a regulatory value with potentially large economic consequences (see Pinto Creek decision).

We believe this background discussion is relevant because maybe the risk management/policy decision to use the SDWA RSCs to harmonize with the CWA HHC should be reconsidered now that states have had time to examine more fully the EPA 2000 guidance. The decision to try to harmonize the development of the MCLG and the CWA HHC may be like trying to harmonize apples and oranges: both are fruit – both are different from each other. Different regulatory programs address the same chemicals and effects in different ways in order to fulfill the requirements of enabling legislation, regulations, and local needs. Applying a default assumption (RSC = 20% to 80%) that might have no effect on a regulatory level (the MCL) from one program, to another program (NPDES) where the assumption can drive huge resource and compliance issues (through requirements to meet HHC in ambient waters) does not necessarily make sense. Trying to harmonize programs or regulatory levels seems like a good idea on the surface, but trying to harmonize programs or regulatory levels that are not completely analogous is not necessarily a good idea.

An alternative to using the 20%-80% range would be to apply 100% as the RSC. 100% has been the RSC value traditionally incorporated into HH criteria development for the non-carcinogens, unless additional data to identify other exposure pathways are available (e.g., the new mercury HH criteria). Maybe this is the way to go until this issue has had more discussion. An inherent assumption in how the RSC for HHC is

<p>developed is that all other sources of the contaminant are required to be considered in the exposure scenario, and the HHC get the “left over” part of the reference dose. This results in the odd situation where, as the contribution of a contaminant from water becomes less and less important (a smaller part of the RfD allowed in water), the HHC get more and more stringent – in effect becomes a bigger and bigger driver for more restrictive limits.</p>	<p>Because other regulatory programs (e.g., FDA action levels and food tolerances, SDWA MCLs, Superfund clean-ups) target lower levels of protection, the CWA program is at the mercy of the regulatory levels set in other programs, and is expected to “clean-up” the waters that are allowed higher levels of pollution than these other sources (even when these other sources may be ongoing sources even after their regulatory requirements have been fulfilled). It would be interesting to have a broader national discussion on how the RfD for any individual chemical is allocated among different regulatory programs. Maybe it would make more economic sense, and more opportunities might be available, to try to cut down the levels of contaminants allowed in other regulatory programs (that are based on cost, feasibility, etc.) so that the CWA criteria could focus only on the designated uses and CWA-regulated pollution sources within the geographic jurisdiction of each state.</p>	<p>Comment 2. This reads like rule language instead of guidance.</p>	<p>Comment 3. This reads like rule language instead of guidance.</p> <p>Comment 1. This statement in the FAQ causes confusion about who has the responsibility for making risk management decisions with regard to both risk level and FCR: EPA regions or</p>
<p>Q5. Should an RSC also be applied to carcinogens? In the case of carcinogens based on linear low-dose extrapolation, the AWQC is determined with respect to the <i>incremental</i> lifetime</p>			

<p>risk posed by a substance's presence in water, and is not being set with regard to an individual's total risk from all sources of exposure. Thus, the AWQC represents the water concentration that would be expected to increase an individual's lifetime risk of carcinogenicity from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources. For human health criteria, this exposure pathway considers consumption of freshwater and estuarine fish and shellfish (as described in the responses to Q1 and Q2) and drinking water ingestion. (see comment 1 at right)</p> <p>EPA recommends that the incremental cancer risk from these exposure pathways not exceed more than 1 in 1,000,000 or 1 in 100,000 for the general population, nor exceed more than 1 in 10,000 for any sensitive sub-population (such as those who may consume a great deal more fish because of a subsistence lifestyle). States and tribes may consider adjusting the risk level according to guidance in the 2000 Human Health Methodology (and mentioned above), particularly if exposure to "other" sources besides water and fish is determined to be significant.</p>	<p>This issue is particularly important, in an immediate sense, for Washington and Idaho. Both states have been told by EPA Region 10 that the Region is considering developing "region-specific" guidance (or some other framework to look at approvable criteria) on HHC, including risk levels and FCRs. The states have also been told that Region 10 thinks "the Oregon outcome was the right outcome." The Oregon outcome included risk management decisions, appropriately made by that state, for a FCR that included salmon consumption and application of that rate to a state-determined risk level. Washington and Oregon are concerned that development of regional guidance will usurp the risk management decisions appropriately and historically made by states, and instead have them made by EPA. If this is the approach then the issue of "rule-by-guidance" becomes important.</p>	<p>Q6. Could a state include a component of marine fish consumption in their FCR for deriving human health criteria?</p> <p>Yes, a state may include consumption of marine species in the FCR. (see comment 1 at right) Coastal States and authorized Tribes that believe accounting for total fish consumption (i.e., freshwater/estuarine and marine species) is more appropriate for</p> <p>Comment 1. As discussed above in the comments on Q2, commercial markets make marine fishery resources available to consumers in all states. Inland states may have just as much, or even maybe more, fish of marine origin sold in their markets than coastal states. This seems to be analogous to the inclusion of consumption of imported fish/shellfish from waters outside</p>
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<p>protecting the population of concern may do so. In the instance where the FCR includes freshwater, estuarine and all marine fish consumption, EPA recommends that states adjust the RSC estimate to reflect a greater proportion of the reference dose being attributed to water intake and the marine-inclusive FCR exposures.</p> <p>Including marine fish in the fish consumption rate may be particularly appropriate if a large proportion of fish consumption for the population to be protected consists of marine fish (such as Salmon) and this exposure is clearly documented. Including marine fish in the fish consumption rate for criteria calculations would provide some calculations that are more stringent than those that don't include marine fish consumption, particularly for chemicals that are highly bioaccumulative.</p>	<p>A serious national public policy discussion needs to take place about what we are trying to achieve by including non-local fish in the basis for water quality criteria that are going to be used to regulate local waters.</p>
<p>Q7. When fish consumption exposure is represented by a distribution of values, what are the appropriate percentiles to choose?</p> <p>In general, EPA considers protection of the general population to be represented by the 90th percentile of a total exposure distribution utilizing a "per capita" fish consumption distribution. If present in the state, subsistence fishers should be considered on a site specific basis. EPA has recommended the 99th percentile of a per capita fish consumption distribution as a surrogate for subsistence fishers, which corresponded to a range of average consumption estimates from actual surveys for subsistence fishers. (see comments 1 and 2) An analysis of protectiveness of the criteria for the general population, recreational fishers and subsistence fishers should be included in the criteria documentation.</p>	<p>Comment 1. We think it is clear from the EPA 2000 guidance, as reiterated in this FAQ, that final criteria development should be underlain by clear statements on risk management decisions made by the states and on the levels of risk/protection that are provided by new HHC. As stated at left, that clarity should apply to "the general population, recreational fishers and subsistence fishers."</p> <p>Note: Idaho's request for assistance in planning and/or conducting a survey of the general population of Idaho was recently refused by EPA. Given this FAQ direction, we would like greater clarification from EPA on why they were not supportive given their statement highlighted at left.</p>